DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2015

Bio Protech Incorporated
% Mr. Kevin Han
Bio Protech USA Incorporated
2601 Walnut Avenue
Tustin, California 92780

Re: K143103
Trade/Device Name: PROPENCIL™ Smoke pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 4, 2015
Received: June 12, 2015

Dear Mr. Han:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143103

Device Name: PROPENCIL™ Smoke Pencil

Indications for Use:

PROPENCIL™ Smoke pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Summary

K143103

SPONSOR:

Bio Protech, Inc.

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Gangwon-do, 200-801

Republic of Korea

Company Contact Person: Daniel Woo

Official Correspondent: Kevin Han, Bio Protech USA Inc.,

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NEW DEVICE: K143103

Proprietary Name: PROPENCIL Smoke Evacuation Pencil

Common/Usual Name: ESU Smoke Evacuation Pencil

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Regulation Number: 878.4400

Product Code: GEI

Device Class: Class II

PREDICATE DEVICES:

LiNA Medical SafeAir (K120454) Smoke pencil

Conmed, Inc. ClearVac (K982309) smoke evacuation accessory with ESU Pencil (K791137)

Indications for Use:

PROPENCIL™ Smoke pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

Device Description:

PROPENCIL Smoke Evacuation pencil consists of two types of disposable Smoke Evacuation monopolar pencils with finger controlled button switch or rocker switch for cutting and coagulation, and also suction cap, tube, hose are all included. All products are sterile, single-use, and disposable. The method of sterilization is Ethylene Oxide. The finger controlled switch is push button or rocker switch and the blade is an uncoated stainless steel electrode or ceramic coated non-stick blade.

PROPENCIL Smoke Evacuation pencil is designed to work with standard electrosurgical generators utilizing a 3-pin monopolar connection port and smoke evacuation units utilizing 8-to-22 hose connector. The tube is located near the electrode tip.

PROPENCIL Smoke Evacuation pencil is available with either a push button or a rocker switch, and some models include an optional holster. Most importantly the suction cap can be replaced with longer ones to extend the length of smoke pencil. The PROPENCIL smoke evacuation pencil has a shelf-life of 36 months.

Substantial Equivalence Chart:

Manufacturer	**Bio Protech Inc.**	**LINA**	**Conmed**
Proprietary Name	PROPENCIL Smoke Evacuation	SafeAir	ClearVac
510(k) Number	K143103	K120454	K982309 (with K791137)
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Product Code	GEI	GEI	GEI

Intended Use	PROPENCIL Smoke Evacuation pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with	The SafeAir Smoke Pencil is designed for general electrosurgical applications and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke	Used in conjunction with the electrosurgical pencil of 510(k) Notification K791137, the accessory is intended to remove smoke generated by electrosurgery.
Operation Function Switches	<CUT> button labeled yellow and proximal to electrode; <COAG> button labeled blue and distal to electrode	<CUT> button labeled yellow and proximal to electrode; <COAG> button labeled blue and distal to electrode	<CUT> button labeled yellow and proximal to electrode; <COAG> button labeled blue and distal to electrode
Power Supply	Monopolar generator supplied by user	Monopolar generator supplied by user	Monopolar generator supplied by user
Monopolar Generator Setting	Max 5.0kV	Max 6.0kV	Max 5.5 kV
Electrical Connector	US 3-Pin	US 3-Pin	US 3-Pin
Smoke Evacuation System	Yes	Yes	Yes
Adjustable Suction Sleeve	Yes	Yes	No
Handpiece Dimensions (Dia x Length)	15.5mm x 190mm	15mm x 190mm	25mm x 190mm
Handpiece Housing Material	ABS Resin	PS Resin	ABS Resin
Suction Sleeve Material	Polystyrene	Polystyrene	Polystyrene
Electrode Length	70 mm	70 mm	70 mm
Electrode Dimension	23 mm x 2.35 mm	17 mm x 2.3 mm	17 mm x 2.3 mm
Electrode Material	Stainless steel and Ceramic coated non-stick blade.	Stainless steel	Stainless steel
Complies with ISO10993	Yes	Yes	Yes

Complies with IEC60601-1	Yes	Yes	Yes
Complies with IEC60601-2-2	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Sterile Processing	Ethylene Oxide	Ethylene Oxide	Radiation

Sterility and Shelf Life Testing:
The method of sterilization for PROPENCIL Smoke Evacuation pencil is EO sterilization.
Accelerated aging tests were conducted according to ASTM F 1980:07, "Accelerated aging of sterile barrier systems for medical devices." The test results indicate The PROPENCIL smoke evacuation pencil has a shelf-life of 36 months.
Validation testing has been completed which confirms the packaging material and meets the requirements of EN ISO 11607-1:2006 "Packaging for terminally sterilized medical devices – Part1: Requirements for materials, sterile barrier systems and packaging systems."
The sterility assurance level (SAL) is 10-6.
The PROPENCIL Smoke Evacuation pencil passed EO residual testing performed according to ISO 10993-7: 2008 Ethylene Oxide Residuals.

Safety and Effectiveness Testing:
Safety testing electrical
Bio Protech, Inc. tested by INTERTEK for the PROPENCIL Smoke Evacuation pencil according to the following standard:

IEC 60601-2-2:2009 (Fifth Ed) for use in conjunction with IEC60601-1:2005

Performance Testing Bench:

1) Smoke evacuation performance test: Bio Protech performed smoke evacuation bench comparison testing to the LiNA SafeAir (K120454) and Conmed (K982309) detachable smoke evacuation accessory attached to ESU pencil (K791137). PROPENCIL Smoke Evacuation pencil outperformed the predicate device in smoke evacuation.

2) Electrical performance test: For this test, EBE65N (6.5" evacuation blade extender with ceramic coating) has been tested by INTERTEK as the worst case (The resistance of the blade increases if the length of the blade is increased. The efficiency of electrical performance is lowered. Therefore we tested EBE65N (6.5" evacuation blade extender with ceramic coating) since EBE65N is longest blade as the worst case). The other blades for PROPENCIL Smoke Evacuation pencil have been tested by Bio Protech inhouse to

verify the electrical performance to be equivalent or better. The other blades are EB25, EB25N, EBE40, EBE40N and EBE65.

3) Thermal zone damage of the cutting and coagulation function test: Bio Protech performed the thermal zone damage of the cutting and coagulation function testing by comparing visually assessed of the Bio Protech PROPENSIL Smoke Evacuation Pencil against LiNA's SafeAir Smoke Pencil (K120454). PROPENCIL Smoke Evacuation pencil outperformed the predicate device in thermal zone damage of the cutting and coagulation.

Performance Testing Animal: Animal testing is not required for this device.

Performance Testing Clinical: Clinical testing is not required for this device.

Conclusion:
PROPENCIL Smoke Evacuation pencil is similar to the predicate devices in intended use, materials and design. The PROPENCIL Smoke Evacuation pencil can be considered an adequate smoke evacuation pencil device concerning safety and efficacy